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Virginia Board of Pharmacy

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Pharmacy Technicians to be Held More Accountable in Dispensing Errors

Prior to registration of pharmacy technicians, the Virginia Board of Pharmacy held only the checking pharmacist responsible for not ensuring accuracy in cases involving dispensing errors. In February 2003, when the registration process was initiated for pharmacy technicians, there was still sentiment on the part of the Board to only open a case against the pharmacist. Today, however, the Virginia Department of Health Professions Enforcement Division is frequently aware of the identity of the pharmacy technician who may have contributed to a dispensing error. This information is obtained either through receiving cases on pharmacy technicians who contributed to dispensing errors, or it is noted as part of an investigation of dispensing error cases.

The issue of whether cases should be open on both the checking pharmacist and the identified pharmacy technician involved with a dispensing error case was discussed at the September 2007 full Board meeting. It was decided that cases should be opened against both the checking pharmacist and the identified pharmacy technician. The Board will consider the appropriate action to be taken on a case-by-case basis.

Reprimand and Monetary Penalty to be Imposed for Unregistered Pharmacy Technicians

It is a violation of law for an unregistered person to perform duties restricted to pharmacy technicians unless that person is currently enrolled in a Board-approved pharmacy technician training program and is within the nine-month time allowance for performing these duties. When such violations are discovered, cases are opened against the pharmacist-in-charge (PIC) allowing this activity and the person unlawfully performing these tasks, provided that person applies for registration as a pharmacy technician, which then gives the Board jurisdiction. Until now, the Board has resolved these cases by issuing a Confidential Consent Agreement (CCA) to both parties. A CCA may only be issued by the Board to resolve a case that involves minor misconduct, where there is little or no injury to a patient or the public and little likelihood of repetition by the person. A CCA includes findings of fact and may include an admission or a finding of a violation. A CCA is confidential and is not considered either a notice or order, but it may be considered by a board in future disciplinary proceedings.

In 2003, the Board decided that this was an appropriate disciplinary action, because the registration of pharmacy technicians was a new requirement. Since that time, the Board has used many avenues to educate interested parties and pharmacists on requirements for registration of pharmacy technicians. The Board, however, continues to receive a number of cases related to this unlicensed activity even though the pharmacy technician registration law has been in place for more than four years. Therefore, the Board has determined that it is time to move beyond the issuance of a CCA to resolve these cases, and has directed staff to now offer a pre-hearing consent order instead of the CCA, with the sanction of a reprimand and a monetary penalty of $250 to the PIC and a reprimand and monetary penalty of $50 to the pharmacy technician registration applicant.

For more information on how to properly register pharmacy technicians, click on *www.dhp.virginia.gov/Pharmacy/pharmacy_faq.htm#TechRegistration.*

Paying Cash for the Remainder of a Schedule II Prescription

Board staff is frequently asked how to handle the dispensing of a Schedule II prescription when a third-party payer will cover only a partial amount of the prescribed quantity, yet the patient is willing to pay cash for the remainder. The Board determined that it could not provide advice on how to accomplish this except that the official dispensing record for the pharmacy will have to accurately reflect one prescription, the total quantity dispensed on that date for that one prescription, and must otherwise meet all requirements of law, to include accuracy of reporting to the Prescription Monitoring Program (PMP). Some pharmacies have asked if two prescription numbers may be assigned to the same prescription in which part of the total quantity dispensed would be assigned to one number for third-party billing, and the remainder assigned to the second number for cash payment. This would not appear to meet record requirements and would appear to provide inaccurate reporting to the PMP. Some pharmacy software programs can accommodate split billing processes, but not all. Pharmacists may want to consult their software vendor for guidance.

Using Stamps to Indicate Pharmacists' Initials

Within Board regulations, there are several regulations that require a pharmacist to initial a document to certify that he or she has checked for accuracy, verified a particular process, etc. In the past, Board interpretation required a manual recording of initials in the pharmacist's own handwriting. However, the Board was recently asked to consider the allowance of a stamp consisting of the pharmacist's initials, since handwritten initials are often illegible, especially if the pharmacist must initial hundreds of times in a day or in cases where there are multiple

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Public Hearing Garners Recommendations on Use of Medication Guides

Participants in a public hearing held in June 2007 by the Food and Drug Administration (FDA) Center for Drug Evaluation and Research suggested ways to improve the FDA Medication Guide program. The program provides for the distribution of FDA-approved written patient information for certain medications that pose serious and significant public health concerns.

FDA officials heard testimony from a member of Congress and 40 individuals representing academia, consumers and consumer groups, the pharmaceutical industry, health care professional groups, practicing physicians, pharmacists, and pharmacy organizations.

Participants acknowledged the importance of patients receiving appropriate risk information in the form of Medication Guides to make informed decisions about certain prescribed medications. Some said the current program is too cumbersome and lacks a standard distribution system. Participants urged FDA to increase awareness of Medication Guides, make them easier to read and understand, move toward facilitating electronic distribution, and consider combining the information contained in Medication Guides with other information such as in Consumer Medication Information.

The public hearing is summarized on the FDA Web site at *www.fda.gov/cder/meeting/medication_guides_200706.htm.*

Reporting Makes a Difference

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In both Institute of Medicine (IOM) reports, *To Err is Human: Building a Safer Health System,* and *Identifying and Preventing Medication Errors,* the importance of error reporting is highlighted. The reports suggest that greater effort is needed to identify medication errors in most care settings, both to measure the extent and scope of errors and to assess the impact of prevention strategies. Although no single recommendation or activity offers a full solution to medical error, error prevention experts agree that successful error reduction strategies depend heavily on responsible detection and open reporting of errors.

According to the IOM report, reporting programs, whether voluntary or mandatory, must satisfy two primary purposes:

1. to hold providers accountable for performance and patient safety; and
2. to provide information that leads to new knowledge and improved patient safety.

Reports to voluntary systems typically come from front-line practitioners or others similarly close to the error, who can best describe the specific conditions that led to that error. Better error descriptions make possible more effective analysis of the system-based causes of errors. This first-hand reporting and the improved analysis it affords has been used by error prevention experts to create a "road map" for improvement that easily and realistically can be extrapolated and implemented at the broadest variety of health care organizations. These practical recommendations for safe practice have been established, published, and widely disseminated throughout the health care community.

Further, voluntary reporting programs have learned that many errors are caused by factors outside the health care practice site and beyond the direct control of a health care practitioner. Thus, safe practice recommendations have been communicated to medical device manufacturers, pharmaceutical companies, automation technology companies, health care reimbursement systems, and others less directly involved in patient care, but nonetheless influential in the safe provision of care.

The success of current voluntary reporting systems also stems from the trust and respect that has typically developed between reporters and recipients who use the information to improve patient safety across the nation. Reporting is perceived to have immense value when those who report an error or potentially hazardous situation can readily see that the information is swiftly acted upon and used confidentially and proactively to develop and publish safe practice recommendations that can prevent errors.

The USP-ISMP Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP) in cooperation with ISMP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern.

Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. Errors, near-errors, or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications.

Providing causative information on actual or potential errors, or near misses to USP and ISMP, which is automatically shared with FDA and the involved manufacturers, has resulted in drug name changes. For example:

- Losec® (error reports indicating mistaken as Lasix®) to Prilosec®,
- Levoxine (error reports indicating mistaken as Lanoxin®) to Levoxyl®,
- Reminyl® (error reports indicating mistaken as Amaryl®) to Razadyne™ (and unfortunately new error reports show Razadyne being mistaken as Rozerem™)

♦ and the most recent, Omacor® (error reports indicating mistaken as Amicar®) to Lovaza.

To those who report medication errors, keep up the great work. The actions resulting in the name changes listed above, alone, demonstrate the tremendous impact you make when you report your experiences to USP-ISMP MERP. Many other error reports have resulted in manufacture label and stock bottle changes. For more information on reporting incidents, visit *www.ismp.org* and click on "Report Errors."

FDA Finds Consumers Still Buying Potentially Risky Medications via Internet

FDA continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by FDA show that consumers who are trying to save money on prescription drugs need not take chances by buying prescription drugs from foreign Internet sites because low-cost generic versions are available in the United States. These findings also indicate that some consumers are likely buying foreign drugs online to avoid having to obtain a prescription from their doctors or health care professionals, as many Web sites do not require a prescription.

FDA urges consumers to obtain prescriptions from their doctors or other health care professionals before using prescription drugs, stating that the use of prescription medications without a prescription is an "intrinsically unsafe practice." FDA also encourages consumers to review *www.fda.gov* for information on buying medications online before making such purchases.

FDA cites the following potential risk factors associated with buying medications from unregulated Internet sellers:

♦ inadequate labeling for safe use;
♦ inappropriate packaging and, therefore, uncertain product integrity;
♦ possible previous withdrawal from the US market for safety or efficacy reasons;
♦ drug-specific risks requiring initial screening and/or periodic patient monitoring;
♦ potential harm or abuse, such as with the use of controlled substances; and
♦ potential drug-drug interactions.

Recent examinations of a sample of drugs shipped to US consumers found several drugs are associated with higher risks if used without the supervision of a doctor or health care professional. For example: the use of warfarin requires close monitoring to prevent stroke or death; amoxicillin and other antibiotics should not be used for self-treatment because of the risk of antibiotic-resistant infections; levothyroxine use requires close monitoring to ensure effective treatment; and clopidogrel may pose increased risk of cardiac events, such as heart attack, if used in suboptimal doses, which might be found in imported tablets.

Improper labeling also presents a risk to consumers. For example, alendronate sodium labeling should warn patients of significant side effects with improper use. In addition, imported eye drop preparations may have been manufactured under unsterile conditions, presenting a risk of contamination that may result in serious infections.

In light of these and other risks associated with medications purchased over the Internet, FDA stresses the importance of obtaining only FDA-approved drugs along with health care provider monitoring.

Death in Canada Tied to Counterfeit Drugs Bought via Internet

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites™ program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

FDA Sets Standards for Dietary Supplements

FDA recently issued a final rule requiring current good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredients. FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at *www.fda.gov/dockets/ecomments.*

The final CGMP and the interim final rule became effective on August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at *www.cfsan.fda.gov/~dms/dscgmps7.html* and a fact sheet at *www.cfsan.fda.gov/~dms/dscgmps6.html.*

More information is available on the FDA Unapproved Drugs Web site at *www.fda.gov/cder/drug/unapproved_drugs/default.htm.*

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pharmacists that may have the same initials. The Board determined that a stamp may be used when recording a pharmacist's initials, but pharmacies should institute policies and procedures for ensuring that each pharmacist's stamp is maintained in a secure manner and not used inappropriately or by another person. Please note, however, that manual signatures are still required for those record-keeping requirements that specify a pharmacist's signature.

Board Appointments

The Board of Pharmacy would like to congratulate John O. Beckner, who was recently reappointed by Governor Tim Kaine to a second four-year term as Board member and Jennifer H. Edwards, who was recently reappointed as the Board of Pharmacy's representative to the Board of Health Professions for a four-year term. Additionally, the Board would like to welcome Gerard A. Dabney who was appointed to a first four-year term as a citizen Board member. Mr Dabney replaces Diane M. Langhorst whose first term expired June 30, 2007. Ms Langhorst's valuable perspective was appreciated by all, and the Board would like to thank her for her time and contributions.

License Renewals and Continuing Education

Renewal notification letters will be mailed in mid-November. This letter will state that it is time to renew licenses via the electronic renewal process on the Board's Web site. The letter will, also, contain a personal identification number (PIN), which may be used when renewing online. If the licensee is accustomed to using a different PIN, he or she may continue to do so, or the licensee may use the newly assigned PIN, which will override any PIN used in the past. As always, licensees are encouraged to renew online. However, if a licensee does not wish to renew online, then he or she may follow the instructions provided on the renewal notification letter for obtaining a renewal form that may be mailed to the Board.

Due to a revenue surplus, the renewal fees for the past two years had been reduced. This year, however, revenues are in line with expenditures, and the full current renewal fees will apply and are as follows: pharmacist active license – $90; pharmacist inactive license – $45; pharmacy technician registration – $25; and pharmacy permit – $270.

In addition to submitting the renewal fee, each pharmacist and pharmacy technician renewing an active status must verify successful completion of all necessary continuing education (CE) hours during the 2007 calendar year. For compliance, pharmacists must obtain 15 hours of approved CE per calendar year, and pharmacy technicians must obtain five hours of approved CE per calendar year. Licensees should not renew a license prior to obtaining the appropriately approved CE. Falsely certifying on the renewal form that you have obtained the required CE may result in disciplinary action being taken by the Board.

CE for pharmacists and pharmacy technicians that meets Board compliance includes programs that have been Board-approved, Accreditation Council for Pharmacy Education-approved, or continuing medical education approved in Category I. It is important to note that national pharmacy technician certification programs, such as the Pharmacy Technician Certification Board (PTCB) examination, that also require CE may accept CE from programs that do not comply with Board regulation; therefore, pharmacy technicians should carefully ensure that they have five hours of CE to satisfy Board requirements prior to renewing their registrations.

If the licensee has failed to obtain CE, he or she may request a one-time extension for no cause shown. Any subsequent extension requests will be granted for good cause only. Such a request must be made in writing, which includes e-mail, and must be made before renewing the license. Be aware that any person who requests an extension will be audited the following year and will be required to submit original CE documents. For example, if the licensee requested an extension at the end of 2006, he or she will be audited in early 2008 and will be required to produce all CE hours required for the 2006 and 2007 renewal periods: 30 hours for pharmacists and 10 hours for pharmacy technicians.

Also, please be aware that the PIC is responsible for ensuring that all pharmacists and pharmacy technicians working in the pharmacy have current and active licenses with the Board. Therefore, as of January 1, 2008, the PIC should verify that all licenses have been renewed. Please refer to guidance documents 110-4 and 110-19 at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm* for helpful information related to CE.

Are You Using the Prescription Monitoring Program?

Registering New Users

The PMP is a tool that assists pharmacists in determining the validity of a prescription by providing a prescription history of a patient for the pharmacist to review. Specifically, the report states the number of drugs in Schedules II, III, and IV that the patient has been dispensed within a particular period of time. It also identifies the names of the multiple pharmacies and multiple prescribers that may be involved and; therefore, may provide enough information to the pharmacist for determining whether the patient is doctor shopping. Prior to submitting a request for a report detailing the dispensing history of a particular patient, the pharmacist or prescriber must first register with the PMP program.

Registration is simple. Pharmacists can visit *www.pmp.dhp.virginia.gov/pmpwebcenter/login.aspx* and click on "Not a User? Register to become a user." Either fill out the online form and click the **submit** button, or print and complete the form, sign, date, and fax it to 804/527-4470. The registration form will be processed, and notification of the registration along with instructions on how to make a request will be sent to the registered user. Consent of the patient is not required in order for a pharmacist to make an inquiry; however, a notification that the pharmacy may use the program must be posted in public view in the pharmacy prior to making requests.

Upcoming Educational Event

Please make plans to join us on Friday, November 16, 2007, when the Virginia PMP and the Virginia Board of Medicine present "TIME TO TEAM UP! PMP & Health Professionals Joining Forces for Patient Care." There is no registration fee for this event, but it is limited to 100 participants and the registration form must be received by November 7, 2007. Coffee and registration begins at 8:30 AM with the conference running from 9 AM - 4 PM. The registration form, along with a listing of scheduled speakers and topics, may be accessed at: *www.dhp.virginia.gov/misc_docs/PmpConf2007flyer.doc.*

New Statistics Released

The results of the 2006 National Survey on Drug Use and Health have been released, and once again prescription drug abuse is a very serious concern. Among young people, prescription drug abuse continues to rise even as the use of illegal drugs stabilizes or decreases. When survey participants were asked where they received their prescription drugs, the overwhelming response was from family or friends. John Walters of the Office of National Drug Control Policy was quoted as saying, "The drug dealer is us."

When counseling a patient, be sure to include information on the proper storage and security of the drug, in addition to the proper disposal of any unused and unwanted prescriptions. Federal guidance written for patients wishing to dispose of dispensed prescriptions is available at *www.whitehousedrugpolicy.gov/drugfact/factsht/proper_disposal.html.*

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